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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,972	01/23/2002	Lenore M. Martin	4705	3036

7590 05/03/2005

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EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,972	MARTIN ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,9 and 10* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/9/03;8/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Renumbering:

Newly presented claims 3-4 (which were previously cancelled) in the amendment dated 4/4/05 are being renumbered as new claims 9 and 10, respectively pursuant to MPEP 608.01(j) and 37 CFR 1.126:

608.01(j) Numbering of Claims

37 CFR 1.126. Numbering of claims.
The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled the remaining claims must not be renumbered. When claims are added, they must be numbered by the applicant consecutively beginning with the number next following the highest numbered claim previously presented (whether entered or not). When the application is ready for allowance, the examiner, if necessary, will renumber the claims consecutively in the order in which they appear or in such order as may have been requested by applicant.

In the next response applicant must provide a new claim set which is consistent with the above.

Status of the Claims

Claims 5, 9 and 10 are currently pending

Claims 5 and 10 (formerly claim 4) are under consideration.

Claim 9 (formerly claim 3) is withdrawn from consideration as being directed to a nonelected invention.

Election/Restrictions

1. Applicant's election with traverse of Group IV (claim 5 drawn to a combinatorial library of oxazole-thiazole compound) in the reply filed on August 6, 2004 and April 4, 2005 is acknowledged. The traversal is on the ground(s) that the examination of: A multistep method of producing an N-protected oxazole/thiazole and a specific N-protected oxazole/thiazole amino acid comprising the structure of formula (3) is not additionally burdensome to search when searching the Library claim. This argument was found persuasive with respect to the specific N-protected oxazole/thiazole but not the multistep method for the following reasons:

a. the search of the formula (12) derivative library does not require a search of a multistep method of the making of a specific intermediate compound and the search of a multiple step method requires additional burdesnome search (e.g. bibliographic) and consideration regarding the search of specific steps, chemical condtions and intermediates;

b. the search of the specific N-protected oxazole/thiazole amino acid is not burdensome insofar that upon consideration (e.g. search and IDS review) of the library claim a reference anticipating this specific compound has been uncovered .

c. finding a reference (e.g. Videnov Agnew Chem. Ed. Engl. 1996 (Vol. 35 No. 13/14) pages 1503-1506) teaching the specific N-protected oxazole/thiazole amino acid compound means that there is no common special technical feature shared by the specific N-protected oxazole/thiazole amino acid compound (e.g. claim 4, renumbered

claim 10) and its manfacture (e.g. claim 3, renumbered claim 9) justifying a lack of unity between the compound and its method of manufacture.

The requirement, as modified, is still deemed proper and is therefore made FINAL.

2. Claim 9 (formerly claim 3) is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Objections

3. Claim 5 is objected to because of the following informalities: "alchohol" is spelled incorrectly. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 10 is rejected under 35 U.S.C. 102(a,b) as being clearly anticipated by Videnov Agnew Chem. Ed. Engl. 1996 (Vol. 35 No. 13/14) pages 1503-1506).

Videnov compound 23 (see page 1504, scheme 3; see also page 1504, right column, first full paragraph) clearly anticipates the N-protected oxazole/thiazole amino acid compound of formula (3) as presently claimed.

7. Claim 5 is rejected under 35 U.S.C. 102(a,b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Videnov Agnew Chem. Ed. Engl. 1996 (Vol. 35 No. 13/14) pages 1503-1506).

The presently claim invention is drawn to :

A "combinatorial" library, of at least two compounds, each compound within the library being "derived from" the solid phase peptide combinatorial syntheses of at least one compound selected from the group consisting of the bridged oxazole (X and/or Y is O) thiazole (X and/or Y is S) compound of formula (12).

Initially, it is noted that:

i. A preamble (e.g. A **"combinatorial"** library) is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951); MPEP.2111.02.

In the present instance the preamble need not be afforded patentable weight since the method of manufacture (e.g. combinatorial syntheses e.g. solid phase) is not necessary for making formula (12) derivatives (e.g. non-combinatorial and/or recombinant and/or liquid phase syntheses can be utilized) and when the preamble and/or the process limitation (e.g. from the solid phase peptide combinatorial syntheses) is removed from the claim, the claim can stand alone.

ii. The presently claimed Library composition (e.g. collection of at least two compounds) of formula (12) derivatives is a product-by-process claim since the

library is defined by its method of manufacture e.g. combinatorial i.e.solid phase peptide combinatorial syntheses.

In this regard, where the claimed and prior art products are identical or substantially identical in structure or composition or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the claimed products and the prior art are the same, applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709,15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The PTO lacks the facilities for making comparisons between prior art and claimed compositions.

Accordingly, a reference teaching the making of two or more compounds within the scope (e.g. a species of and/or comprising formula 12) of the presently claimed bridged oxazole/thiazole formula (12) compound(s) would anticipate claim 5 (e.g. as constituting derivatives of formula 12) regardless of means of manufacture.

The Videnov reference teaches the successive manufacture of compounds (21, 22 and 23) (see page 1504, scheme 3; see also page 1504, right column, first full paragraph) all of which are within the scope of the bridged oxazole/thiazole formula (12) compounds presently claimed (see formula 12 wherein X is O, Y is S; R5/R6 are H; R1 is Oet or OH, R is H and R2 is Boc/Fmoc; which are subsequently used as intermediates to synthesize (e.g. by solid phase peptide syntheses) microcin B17 which is also within the scope of formula (12) see present specification at page 1; fig. 5.

Accordingly, Videnov teaches a collection (e.g. library) comprising formula 21 and 22 ; formula 22 and 23; 21, 22 and 23; or any of these combinations further comprising microcin B17. It is noted that compounds 22 and 23; and 22, 23 and microcin B17 can be deemed to be derived from reference compound 21.

8. Claim 5 is rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Roy et al. Chemistry and Biology (published April 19, 1999) Vol. 6 (5) pages 305-318.

The presently claim invention is drawn to :

A "combinatorial" library, of at least two compounds, each compound within the library being "derived from" the solid phase peptide combinatorial syntheses of at least one compound selected from the group consisting of the bridged oxazole (X and/or Y is O) thiazole (X and/or Y is S) compound of formula (12).

Initially, it is noted that:

i. A preamble (e.g. A **"combinatorial"** library) is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951); MPEP.2111.02.

In the present instance the preamble need not be afforded patentable weight since the method of manufacture (e.g. combinatorial syntheses e.g. solid phase) is not necessary for making formula (12) derivatives (e.g. non-combinatorial and/or recombinant and/or liquid phase syntheses) can be utilized and when the preamble and/or the process limitation (e.g. from the solid phase peptide combinatorial syntheses) is removed from the claim, the claim can stand alone.

ii. The presently claimed Library composition (e.g. collection of at least two compounds) of formula (12) derivatives is a product-by-process claim since the library is defined by its method of manufacture e.g. combinatorial i.e.solid phase peptide combinatorial syntheses.

In this regard, where the claimed and prior art products are identical or substantially identical in structure or composition or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the claimed products and the prior art are the same, applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709,15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The PTO lacks the facilities for making comparisons between prior art and claimed compositions.

Accordingly, a reference teaching the making of two or more compounds within the scope (e.g. a species of and/or comprising formula 12) of the presently claimed

bridged oxazole/thiazole formula (12) compound(s) would anticipate claim 5 (e.g. as constituting derivatives of formula 12) regardless of means of manufacture.

Roy et al. disclose a recombinantly made library (2 or more compounds) of microcin B17 analogs which comprise the presently claimed formula (12) core structure and thus anticipate the presently claimed invention. E.g. see Roy et al. abstract and Fig. 1).

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable as obvious over Videnov Agnew Chem. Ed. Engl. 1996 (Vol. 35 No. 13/14) pages 1503-1506), Videnov Agnew Chem. Ed. Engl 1996 (Vol. 35 No. 13/14) pages 1506-1508 [herein the Videnov references] and Pavia et al. WO 95/04277 (2/95).

The presently claim invention is drawn to :

A "combinatorial" library, of at least two compounds, each compound within the library being "derived from" the solid phase peptide combinatorial syntheses of at least one compound selected from the group consisting of the bridged oxazole (X and/or Y is O) thiazole (X and/or Y is S) compound of formula (12).

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i. A preamble (e.g. A **"combinatorial"** library) is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15

(CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951); MPEP.2111.02.

In the present instance the preamble need not be afforded patentable weight since the method of manufacture (e.g. combinatorial syntheses e.g. solid phase) is not necessary for making formula (12) derivatives (e.g. non-combinatorial and/or recombinant and/or liquid phase syntheses) can be utilized and when the preamble and/or the process limitation (e.g. from the solid phase peptide combinatorial syntheses) is removed from the claim, the claim can stand alone.

ii. The presently claimed Library composition (e.g. collection of at least two compounds) of formula (12) derivatives is a product-by-process claim since the library is defined by its method of manufacture e.g. combinatorial i.e.solid phase peptide combinatorial syntheses.

In this regard, where the claimed and prior art products are identical or substantially identical in structure or composition or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the claimed products and the prior art are the same, applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709,15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The

PTO lacks the facilities for making comparisons between prior art and claimed compositions.

Accordingly, a reference teaching the making of two or more compounds within the scope (e.g. a species of and/or comprising formula 12) of the presently claimed bridged oxazole/thiazole formula (12) compound(s) would anticipate claim 5 (e.g. as constituting derivatives of formula 12) regardless of means of manufacture.

The Videnov references teach the successive manufacture of compounds (21, 22 and 23) (see page 1504, scheme 3; see also page 1504, right column, first full paragraph) all of which are within the scope of the bridged oxazole/thiazole formula (12) compounds presently claimed (see formula 12 wherein X is O, Y is S; R5/R6 are H; R1 is Oet or OH, R is H and R2 is Boc/Fmoc; which are subsequently used as intermediates to synthesize microcin B17 (by solid phase peptide syntheses) which is also within the scope of formula (12) see present specification at page 1; fig. 5. Accordingly, the Videnov references (separately or in combination) teach a collection (e.g. library) comprising formula 21 and 22; formula 22 and 23; 21, 22 and 23; or any of these combinations further comprising microcin B17. It is noted that compounds 22 and 23 and 22, 23 and microcin B17 can be deemed to be derived from reference compound 21.

Even assuming arguendo, that the presently claimed "preamble" and "process limitation" are afforded patentable weight (e.g. solid phase combinatorial syntheses) claim 5 would nevertheless be rendered obvious over the combined teaching of the Videnov and Pavia references.

Although teaching the use of intermediate compounds within the scope of formula 12 to form microcin B17 using solid phase peptide syntheses the Videnov references fail to teach combinatorial solid phase peptide syntheses of analogs of microcin B17.

However, In this regard, it is noted that the Videnov references provides explicit motivation to make microcin B17 analogs:

"The preparation of the oxazole- and/or thiazole-derived amino acids described above enabled us to synthesize fully active microcin B17 [13], and **the use of these and related building blocks for the syntheses of further bioactive products** (e.g. analogs) is the object of intense research" (e.g. see page 1504, right column, last paragraph) (emphasis provided)..

In this regard, the Pavia reference teaches the advantages (e.g. high throughput screening of libraries for diverse peptide mimic lead compounds: see pages 1-4) of using solid phase peptide combinatorial syntheses including the use of scaffolds comprising fused oxazole/thiazole compounds analogous in structure to those presently claimed. E.g. see Pavia Abstract; page 5 structure (wherein X, Y, Z are O/S/N and M1 is a bond); and claims.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to utilize the Pavia reference combinatorial solid phase peptide techniques for the benefits therefrom (e.g. high throughput screening) in order to obtain "further bioactive products" (e.g. analogs) of microcin B17 as suggested by the Videnov references.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

April 28, 2005
BC